PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Toru SANO, et al.

Docket No: Q88016

Appln. No.: 10/536,798

Group Art Unit: 1723

Confirmation No.: 4489

Examiner: Not Assigned

Filed: May 27, 2005

For: SEPARATION APPARATUS AND SEPARATION METHOD

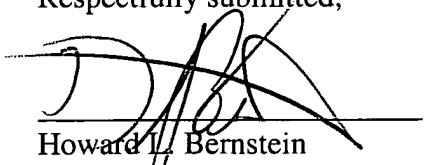
SUBMISSION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT (IPER)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

For the Examiner's convenience, enclosed herewith is a copy of the English translation of the International Preliminary Examination Report (IPER). It is assumed that copies of the cited references as required by §371(c) will be supplied directly by the International Bureau, but if further copies are needed, the undersigned will undertake to provide them upon request.

Respectfully submitted,



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Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference NE-70141WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/015260	International filing date (*day/month/year*) 28 November 2003 (28.11.2003)	Priority date (*day/month/year*) 29 November 2002 (29.11.2002)
International Patent Classification (IPC) or national classification and IPC G01N 1/10, 27/26, 27/62, 30/48, 33/48, 35/08, 37/00, B01D 57/00, 57/02, B81C 1/00		
Applicant NEC CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
28 November 2003 (28.11.2003)	05 August 2004 (05.08.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/015260

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
Those elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-9	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 2001-515216 A (CEPHEID), 18 September 2001 & WO 99/009042 A1 & AU 8906698 A & CA 2301309 A & EP 1003759 A & US 2001-12612 A1

Document 2: JP 10-506991 A (Abbott Laboratories), 7 July 1998 & WO 96/010747 A1 & CA 2195875 A & EP 783694 A & US 5952173 A1

Document 3: JP 2002-524755 A (Advion Biosciences Inc.), 6 August 2002 & WO 00/015321 A1 & CA 2343055 A & AU 5800499 A & EP 1113850 A & US 123153 A1

Document 4: WO 2002/023180 A (Hitachi, Ltd.), 21 March 2002

Claims 1, 2 and 5

Document 1 (see paragraphs [0054] and [0055] in particular) sets forth a microfluidic device for separating a desired substance such as nucleic acid in a fluid specimen from other substances, wherein the extraction chamber has an inner adsorption surface which captures a desired substance from a fluid specimen when a fluid specimen flows continuously through said chamber; said inner adsorption surface is formed from rows of pillars or columns, and said pillars or columns are covered with a material having a strong bonding affinity with the desired substance.

Document 2 (see [abstract], [claims]) sets forth an analysis device which determines the presence and/or quantity of substances being analyzed in the specimen sample, wherein said device has a surface which provides a covalently bonded or non-covalently bonded fixing reagent. Said analysis device comprises a structural array which enables said fixing reagent to bond to a substance selected from the substance being analyzed, analogs of the substance being analyzed, auxiliary bonding elements and marker reagents; and a plurality of flow passages through which the aforementioned specimen sample containing the aforementioned substance being analyzed, analogs of the substance being analyzed, auxiliary bonding elements or marker reagents flows, and the aforementioned substance being analyzed, analogs of the substance being analyzed, auxiliary bonding elements or marker reagents are dispersed over the entire width, bonding to the aforementioned fixing reagent.

Document 3 (see paragraphs [0114] to [0136] in particular) sets forth a microchip liquid chromatography device, wherein the separation channel is provided with a plurality of separation columns, the surface of said separation columns is covered with a reagent, and components are separated by having the specimen to be analyzed flow past the surface of the adjusted separation columnar bodies.

Document 4 (see [embodiment 1], [embodiment 2]; fig. 1 to 7 in particular) sets forth a feature wherein in order to extract a specific component in a liquid specimen, protrusions are provided, comprising a linking member which bonds with a specific component in the passage of the extraction part, and by having the specific component come into contact with said protrusions, said

specific component is bonded to the aforementioned protrusions.

Therefore documents 1 to 4 disclose a separation device wherein a layer of a substance to be adsorbed which selectively adsorbs or bonds to a specific substance is provided to a separation part provided with narrow micro-passages or protrusions, and it would be easy for a person skilled in the art to conceive of the invention set forth in claims 1, 2 and 5 in the light of the inventions set forth in documents 1 to 4.

Claims 3, 4, 7 and 8

Document 1 (see paragraphs [0085] to [0090] in particular) sets forth a feature in addition to the aforementioned matters, wherein electrodes are formed on the passages and protrusions, and by applying a voltage of the opposite charge of the desired substance to said protrusions, bonding with the desired substance is promoted.

It would therefore be easy for a person skilled in the art to conceive of the inventions set forth in claims 3, 4, 7 and 8 in the light of documents 1 to 4.

Claim 6

As described above, document 2 indicates that auxiliary bonding elements are bonded to a fixing reagent, and in the field of immunological analysis it is common general technical knowledge to bond a reagent fixed to a carrier and a substance to be analyzed with a spacer interposed therebetween.

Therefore it would be easy for a person skilled in the art to conceive of the invention set forth in claim 6 in the light of the inventions set forth in documents 1 to 4 and the aforementioned common general technical

knowledge.

Claim 9

When carrying out analysis using MALDI-MS, it is common general technical knowledge to carry out pre-treatment of protein samples, such as separation, oxygen consumption and drying, and it would be easy for a person skilled in the art to carry out all or part of these steps on a microchip.

It would therefore be easy for a person skilled in the art to conceive of the invention set forth in claim 9 in the light of the inventions set forth in documents 1 to 4 and the aforementioned common general technical knowledge.